

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
Y. ROCKY TSAO
FISH & RICHARDSON P.C.
225 FRANKLIN STREET
BOSTON, MASSACHUSETTS 02110

PCT

WRITTEN OPINION

(PCT Rule 46)

Docketed By Practice Sys

Resp to writ. op due
12-25-03

Foreign Act due
12-25-04 (004001)

Initials: nm

Date of Mailing
(day/month/year)

11/25/03

Applicant's or agent's file reference

13062-004WO1

REPLY DUE

within 1 months/days from
the above date of mailing

International application No.

PCT/US02/26444

International filing date (day/month/year)

20 August 2002 (20.08.2002)

Priority date (day/month/year)

10 September 2001 (10.09.2001)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): C12P 21/08, 21/00; C12N 15/00, 15/63; 3/531 and US Cl.: 436/547, 548; 435/69.1, 69.6, 70.21

Applicant

ABGENOMICS CORPORATION

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 20 December 2004 (20.12.2004)

Name and mailing address of the IPEA/US

Mail Stop PCT, Attn: IPEA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703)305-3230

Authorized officer

Ron Schwadron, Ph.D.

Telephone No. 703 3080196

Docketed By Billing Secretary

Due Date: 12-25-03

Deadline: 12-25-03

Initials: CYT

Form PCT/IPEA/408 (cover sheet)(July 1998)

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FISH & RICHARDSON, P.C.
BOSTON OFFICE

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From the
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Y. ROCKY TSAO
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BOSTON, MASSACHUSETTS 02110

PCT

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference 13062-004WO1		Date of Mailing (day/month/year) 25 NOV 2003
International application No. PCT/US02/26444		REPLY DUE within 1 months/days from the above date of mailing
International filing date (day/month/year) 20 August 2002 (20.08.2002)	Priority date (day/month/year) 10 September 2001 (10.09.2001)	
International Patent Classification (IPC) or both national classification and IPC IPC(7): C12P 21/08, 21/00; C12N 15/00, 15/63; G01N 33/531 and US Cl.: 436/547, 548; 435/69.1, 69.6, 70.21		
Applicant ABGENOMICS CORPORATION		

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2. This opinion contains indications relating to the following items:
 - ☒ Basis of the opinion
 - ☐ Priority
 - ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - ☐ Lack of unity of invention
 - ☒ Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - ☐ Certain documents cited
 - ☐ Certain defects in the international application
 - ☐ Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

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Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer Ron Schwadron, Ph.D. Telephone No. 703 3080196
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WRITTEN OPINION

International application No.

PCT/US02/26444

I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☒ the description:
 - pages 1-17, as originally filed
 - pages NONE, filed with the demand
 - pages NONE, filed with the letter of _____
- ☒ the claims:
 - pages 18-20, as originally filed
 - pages NONE, as amended (together with any statement) under Article 19
 - pages NONE, filed with the demand
 - pages NONE, filed with the letter of _____
- ☒ the drawings:
 - pages 1, as originally filed
 - pages NONE, filed with the demand
 - pages NONE, filed with the letter of _____
- ☒ the sequence listing part of the description:
 - pages 1-2, as originally filed
 - pages NONE, filed with the demand
 - pages NONE, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

WRITTEN OPINION

International application No.
PCT/US02/26444

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1-26</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-26</u>	NO
Industrial Applicability (IA)	Claims <u>1-26</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-26 lack an inventive step under PCT Article 33(3) as being obvious over US Patent 6,146,845 in view of US Patent 5,959,171.

US Patent 6,146,845 discloses a fusion protein containing an Fc domain of Ig (see column 10). US Patent 6,146,845 discloses a fusion protein containing a marker which facilitates purification of the fusion protein such as hexa-histidine (see column 5). US Patent 6,146,845 discloses nucleic acids encoding such fusion proteins (see columns 5 and 10). US Patent 6,146,845 discloses recombinant production of said fusion proteins (columns 7 and 8) including purification of said protein from a lysate using affinity chromatography. The art recognizes use of antibodies in affinity chromatography purification including use of antiFc antibodies to purify Fc containing molecules or use of antilabel antibodies to purify fusion proteins containing a label. The use of transgenic animals for the recombinant production of fusion proteins is known in the art (see US Patent 5,959,171, abstract and column 2). US Patent 6,146,845 discloses that such peptides can be used to produce antibodies (polyclonal or recombinant or monoclonal) using art known techniques (see columns 9 and 10). US patent 6,146,845 discloses Fc fusion proteins containing a cleavable Fc region (see column 10).

----- NEW CITATIONS -----

US 5,959,171 A (Hytinen et al.) 28 September 1999, see entire document.

WRITTEN OPINION

International application No.
PCT/US02/26444

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.